REMARKS

The following remarks are made in response to the Office Action mailed April 7, 2005. Claims 22, 25-30, 32-39, and 50-66 were rejected. With this Response, claims 22, 32, 53, and 65 have been amended. Claims 22, 25-30, 32-39, 50-58, and 59-66 remain pending in the application and are presented for reconsideration and allowance.

Claim Rejections under 35 U.S.C. § 103

In the Office Action, claims 22, 24-30, and 32-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff U.S. Patent No. 6,471,089 ("Liff") in view of Boyer U.S. Patent No. 6,202,923 ("Boyer").

Applicant's amended independent claim 22 specifies a patient's intelligent drug dispensing appliance which comprises a controller, a reservoir, a drug delivery mechanism, and a data network interface.

As admitted in the Office Action, Liff fails to disclose dispensing unpackaged pharmaceuticals. However, as detailed in relation to Applicant's claim limitations, Liff as well as Boyer, lack much more. Both Liff and Boyer are different types of devices with different purposes than Applicant's patient's appliance.

Among other differences, Liff fails to disclose the drug delivery mechanism and reservoir as specified in Applicant's independent claim 22. In particular, Liff fails to disclose a drug delivery mechanism configured to controllably dispense the unpackaged pharmaceutical tablets directly from the reservoir to the individual patient as individual doses over time according to a treatment regimen in response to signals from the controller.

As admitted in the Office Action, Liff fails to dispense unpackaged pharmaceuticals. In particular, Liff fails to disclose a reservoir holding unpackaged pharmaceutical tablets and fails to disclose a drug delivery mechanism that dispenses unpackaged pharmaceutical tablets. Rather, in Liff, the system includes, among other things, an automated apparatus for dispensing bottles. The apparatus includes a cabinet housing for storing a variety of bottles of pharmaceuticals in a plurality of bins. Each bin stores a particular variety of bottles where each bottle typically contains a plurality of unit doses. See Liff at Column 2, lines 19-27. The bins are vertically-disposed columns shaped to store a plurality of bottles stacked vertically and each bottle is sealed and contains a selected number of doses. See Liff at

Column 2, lines 51-54; see also Column 6, line 2 and lines 30-33; see also Column 12, lines 53-68.

Of equal importance, Liff apparently does not dispense unpackaged pharmaceutical tablets directly to an individual patient because Liff is directed to a complete **in-office** dispensing system, see Liff at Column 2, lines 13-14. This system is apparently directed at the issue of filling weekly or monthly prescriptions. Liff at Column 2, lines 5-7. A patient does not fill prescriptions: a pharmacist does.

This difference is reflected in Applicant's claim, which specifies a patient's drug dispensing appliance and not an office's dispensing appliance, not a clinic's dispensing appliance, and not a pharmacist's dispensing appliance. This difference is significant because unpackaged pharmaceutical tablets are in an uncontrolled form unless placed within a pharmacy bottle (as in Liff) or within a dispenser (as in Boyer), such as Applicant's patient's appliance. The unpackaged nature of the pharmaceutical tablets in the reservoir (and as dispensed) necessarily makes the appliance personal to the individual patient. In contrast, in Liff the pharmaceutical is only dispensed in a packaged form, as admitted in the Office Action.

Moreover, because Applicant's drug dispensing appliance is configured for dispensing an unpackaged pharmaceutical for an individual patient and not for pharmacists, doctors, hospital wards, etc., it is sized and shaped as a patient's appliance for this purpose because it dispenses pharmaceutical tablets for an individual. The size of the appliance is based on the reservoir being sized to hold the individual doses for the prescription treatment regimen. It is not sized or shaped to dispense packaged (bottled) pharmaceuticals in volume, as in Liff and is not sized for pharmacy use in filling prescriptions, as in Boyer.

In contrast, the system in Liff, as shown in the Figures 1-19, reveals a relatively large system apparently intended for commercial or institutional use, and not as an appliance personal to an individual or single patient, such as a patient's drug dispensing appliance as claimed by Applicant. One example in Liff that reveals its intended scale is that a plurality of the cabinet housings can be installed in a modular or daisy-chained configuration. See Liff at Column 2, lines 47-48. Among many other examples of Liff's larger scale and non-personal use, Liff also discloses that packaged pharmaceuticals are redistributed from each municipal service center 106 to each remote control dispenser 108 in its region (Figure 2). See Liff at

Column 12, lines 65-67. Pre-packaged multiple dose pharmaceuticals are available to practitioners (not patients) at the health care facility for immediate filling of patient prescriptions. Liff at Column 5, lines 4-5. These passages reveal a physicians' system or clinic's system, not a patient's appliance.

In addition, the Figures and description of Liff reveal that the bulky system in Liff is not suited or practical for dispensing unpackaged pharmaceutical tablets directly to an individual patient over time according to a treatment regimen in response to signals from the controller. One example of a typical treatment regimen comprises a pharmaceutical taken as a ten day course of antibiotics, taken one dose per day (or even twice a day), over a ten day period. In other words, the individual unit doses are taken over time. The controller directs the dispensing to execute the treatment regimen. Patients cannot and do not share their treatment regimen with other patients. Accordingly, a patient's appliance, and its reservoir, is sized no bigger than to hold the doses for that treatment regimen.

As revealed throughout the entirety of Liff, Liff is geared to hold multiple bottles, for multiple patients and therefore must be sized on a much larger scale than a patient's appliance.

Further in this regard, Applicant notes that it appears that the Office Action does not reflect treatment of the claim limitation of an individual **patient** in Applicant's amended independent claim 22, as the Office Action still refers to language of an "individual" as a doctor, nurse, but does not address an "individual patient" which clearly is not a doctor, nurse, or pharmacist. An individual patient cannot be construed to be a hospital, a physician or a nurse. This distinction is important, as it relates to the handling of the pharmaceuticals in unpackaged form for direct dispensing to the actual consumer of the pharmaceutical (the one who will ingest the pharmaceutical). Again, this distinction is further reflected in other claim language, namely, a patient's drug dispensing appliance.

With regard to other language in Applicant's claims that does not appear to be addressed completely, Applicant also notes that the Office Action is still addressing claims 23 and 24 (page 4 of the Office Action). Claims 23 and 24 were canceled in the last Amendment. Accordingly, it appears that the Office Action does not appear to address a current version of Applicant's claims. In a sincere interest to further prosecution of this case, Applicant respectfully requests that the entire set of claims in their current form be reviewed

with regard to the rejections made in detail to facilitate expeditious communications regarding the subject matter.

In this regard, Applicant also notes that the Office Action still refers to claim 31. Claim 31 was cancelled in the Amendment on which the Office Action is based.

In addition, the Office Action is still referring to claim language regarding the reservoir ("at least one of tablets, liquids, or gases") which is no longer in Applicant's claims (22, 32, 36, 53, and 54).

Regarding Applicant's claim 22, as previously explained in earlier Responses, Liff dispenses bottles because it is stationed in a health care facility and therefore dispenses pharmaceuticals to many different patients, not to a single patient. Accordingly, the bottles maintain separation of the different types of pharmaceuticals. Liff also uses a card reader for patients to receive a card 39 from a patient to receive their medication. See Column 6, lines 24-35. The card reader is necessary in Liff because the bottles of Liff can be dispensed to many different patients, not just one individual patient, and the card/card reader distinguishes between the different potential recipients of the bottles.

Finally, an additional aspect regarding Applicant's **patient's** intelligent drug dispensing appliance is that the term "patient's", refers to ownership or an one-to-one relationship between the appliance and a unique patient (as opposed to many patients), and that since the appliance is for a unique patient, the pharmaceutical in the reservoir need not be packaged within a bottle, nor access-triggered with a card, as in Liff's system for many patients at institutions, such as prisons. See Liff at Column 6, lines 24-35. Accordingly, the limitation of the intelligent drug dispensing appliance being a patient's intelligent drug dispensing appliance invokes ownership or exclusiveness between the patient and the appliance, and consequently it is suitable for the appliance to dispense tablets, without a bottle, directly to the patient. This feature is not present in Liff, as the drug dispensing cabinet is not owned by or for exclusive use by a single patient, but used by many patients, doctors, nurses, etc, and consequently handles bottles of pills, and uses card readers to allow access to the bottles, thereby enabling differentiation between different patients, and necessarily not dispensing tablets in unbottled form directly from the cabinet.

Dispensing pharmaceuticals is not like receiving ordinary items (e.g., candy) from a common vending machine, in which any customer can legally receive the contents dispensed. Pharmaceuticals require controlled dispensing to protect the patient and the public. In Applicant's claimed appliance, since it's a patient's appliance, it makes sense to direct dispense tablets directly to a patient in unpackaged form, because the patient is the individual receiving those tablets. In contrast, since Liff is placed in a health care facility or institution, direct dispensing of pharmaceuticals in unbottled, i.e., unpackaged form would be hazardous as any person could potentially receive the pharmaceutical and the different pharmaceuticals cannot be mixed together.

Finally, the distinctive nature of Applicant's patient's appliance as defined by all of the above highlighted limitations (an individual patient, a patient's appliance, a reservoir holding an unpackaged pharmaceutical tablets, direct-to-patient dispensing as individual unit doses, a treatment regimen, etc.) is further reinforced by the limitation that the patient's intelligent drug dispensing appliance is sized and shaped, **based on the reservoir being sized to hold the individual doses of the unpackaged pharmaceutical tablets for the treatment regimen**, for placement proximate to the individual patient remote from a health care facility. As previously explained regarding Liff, the system in Liff is sized for institutional use, and is not sized for use personal to an individual patient. The size of the system in Liff would be extremely impractical for holding unpackaged pharmaceuticals for one individual patient to follow that individual patient's treatment regimen.

For all of the above reasons, the system in Liff and Applicant's claimed patient's appliance are simply different in kind, and not merely different in minor degrees as portrayed in the Office Actions.

In addition, Applicant's patient drug dispensing appliance includes a data network interface. Figure 13A (and accompanying text) of Liff cited in the Office Action regarding this feature describes a remote pharmacist workstation 314 (which is part of a larger system) and its software – not a patient's appliance that directly dispenses pharmaceuticals to the individual patient. Figures 13A-13K (and the accompanying description) in Liff reveal that operation of that system is not performed by a patient but by a pharmacist, a technician, or other personnel.

Moreover, the system and software in Liff does not send a data message from the patient's appliance to/from a health care service provider (or pharmaceutical supplier). Instead, the system in Liff sends a message from a remote dispenser 214 of the type used in a physician office or clinic. Figure 14T of Liff, as cited in the Office Action, does not disclose sending data messages, but rather monitoring inventory, such as the number of **bottles** in each RCD bin or column of a remote dispenser (RCD).

In contrast, Applicant's claimed patient's appliance obtains refills for an individual patient only via a data network interface. The data network interface is coupled to the controller of the appliance and is configured to send, and to receive, a data message regarding the pharmaceutical over a data network through the data network interface to and from, respectively, at least one of a health care service provider and a pharmaceutical supplier. The data message **from** the patient via the patient's intelligent drug dispensing appliance (not from a physician or from technician at a physician's office) identifies the patient for whom the unpackaged pharmaceutical is required and the identity of the pharmaceutical. Accordingly, the data message sent/received to and from Applicant's claimed patient's appliance is regarding a pharmaceutical for an individual since it's that patient's intelligent drug dispensing appliance, and not a bottle-dispensing cabinet for multiple patients as in Liff. Therefore, Liff fails to disclose the data network interface as claimed by Applicant.

Boyer fails to cure the many deficiencies of Liff.

First, Boyer is also not a patient's appliance. As illustrated in Figures 1-8, and described throughout), Boyer is directed to the inner workings of a pharmacy, and interactions between pharmacists, technicians, and their communication in preparation of delivering a filled prescription 12 to patient 3. In particular, Boyer discloses dispensing multiple doses into one vial (e.g., bottle) via dispenser 22 at the pharmacy. Boyer at Column 7, lines 50-67 and Column 8, lines 1-15. In Boyer, the pharmacy representative gives the vial (containing doses of the pharmaceutical) to the patient when the patient picks up bottle/vial – the doses are not dispensed individually over time from a patient's appliance directly to the patient, as claimed by Applicant.

Accordingly, in Boyer, an automated pharmacy is described in which a patient plays no role except to request that a prescription be filled (Boyer at Column 6, lines 14-20), and

except to receive a package or vial containing a pharmaceutical from a technician or pharmacist. See Boyer at Figure 1. See Boyer at Figure 3, which broadly illustrates an environment in which "medication is ordered, prepared, and delivered to a patient in a hospital or other institutional health care facility" (Column 7, lines 63-65). Moreover, throughout Boyer, the handling of pharmaceutical is described with nearly constant interaction of a pharmacist or technician, with multiple checking/confirmation that the correct pharmaceutical is being handled. Patient 3 is not present or proximate to dispenser 22, as only pharmacy personnel have access to dispenser 22. Patient 3 only gets access to a filled prescription 12 which is in a vial or bottle, as shown in Figures 7-8. All of the interaction described in Boyer, including operations of dispenser 22, is isolated from the patient 3.

Accordingly, Boyer does not cure the deficiencies of Liff regarding an unpackaged pharmaceutical since Boyer fails to disclose dispensing unpackaged pharmaceuticals directly from the appliance to a patient via a patient's appliance. Boyer, like Liff, discloses placement of the pharmaceutical in a bottle (vial) prior to the patient receiving the prescription pharmaceutical, just as any patient would receive a conventionally filled prescription at virtually any conventional retail pharmacy.

Boyer does not cure the deficiencies of Liff regarding a size/shape of a patient's appliance since the system in Boyer apparently is directed exclusively to a pharmacy operation and not for an individual patient.

Applicant notes that it is unclear how the Office Action is using the word "bedside" as cited in the Office Action, since that term does not appear in Applicant's claim nor in Boyer. While Applicant does specify a patient's appliance for use proximate to an individual patient, Boyer deals with a dispenser operated exclusively within a pharmacy. Liff focuses on facilities, such as a physician's office.

Moreover, numerous other assertions on page 6-7 of the Office Action are made regarding Boyer which do not appear to be disclosed in Boyer. First, nothing in Boyer teaches, suggests, states or otherwise discloses that dispenser 22 is sized or shaped for non-hospital placement proximate to the individual patient. As described in Boyer, it is used within a pharmacy in a manner controlled by pharmacists and/or technicians to be **not** accessible by patient 3.

In another instance, the Office Action asserts that Boyer discloses a hospital management system. Boyer simply describes an automated pharmacy. Liff also does not describe a hospital management system but describes in its Summary of the Invention, a "complete **in-office** dispensing system. This enables drug prescription dispensing in volume by a physician, pharmacist, or other licensed practitioner directly to the patient at a clinic, group practice, or other location outside a pharmacy or hospital (emphasis added). See Liff at Column 2, lines 10-19.

Applicant also contests the assertion in the Office Action regarding a suggestion (to combine Liff and Boyer) in Boyer to efficiently monitor and track unpackaged pharmaceutical doses, increase workflow, and reduce errors (citing Boyer Column 4, lines 20-32). A patient using a patient's appliance, as claimed by Applicant, is not concerned with a "workflow" configuration "as needed in any pharmacy" or that the system "can be used in pharmacies of any size", as described in the cited passage of Boyer. With a patient's appliance, the patient is simply interested in having the tablets dispensed to them. Accordingly, one skilled in art, having the patient's interest in mind in designing a patient's appliance, would see Boyer for what it is: a pharmacy including a dispenser used in the pharmacy, by the pharmacy to fill a bottle with a pharmaceutical so a patient at the pharmacy can purchase the bottle containing their prescription pharmaceutical, and then go home with their bottled prescription pharmaceutical.

With regard to the description of Liff in the Office Action regarding lowering cost over centrally located devices, the patient is simply interested in receiving their pharmaceutical tablets in a convenient manner from their appliance and is not concerned with the pros and cons of decentralized unit-based dispensing devices versus centrally located devices, as a physician, pharmacy, hospital, etc would be concerned. Accordingly, one skilled in art, having the patient's interest in mind in designing a patient's appliance, would see Liff for what it is: a prescription dispenser primarily targeted at physician's offices, clinics, and other places that have sufficient resources to purchase a large system to hold and deliver dozens of prescription bottles too many different patients at the in-office setting.

Accordingly, both Liff and Boyer disclose systems that cater to pharmacists and doctors, but not to patients. The assertion in the Office Action regarding a desire to dispense bulk drugs and networking dispensers has little to do with direct dispensing to a patient so the

patient can follow their treatment regimen by taking each dose when it's dispensed. The focus of the claims of this patent application is a patient's appliance, as thoroughly detailed above. Applicant does not face the burden of proving whether one skilled in the art could have potentially made a device based on a combination of Liff and Boyer while accounting for the needs of a health care system, a doctor's office, or a pharmacy.

The relevant question is whether one skilled in the art would have looked to Liff and/or Boyer, in designing an appliance directed to the needs of the patient, namely, directly receiving their unpackaged doses of a prescription from that appliance. The patient is not interested in bulk dispensing of pharmaceuticals and meeting the needs of pharmacies or doctors. The patient is not interested in regulating drug dispensing for cost in the same way a pharmacist, doctor, or clinic would. A patient also would not be interested in accounting and inventory algorithms to enable bulk drug dispensing. Again, the patient for which Applicant's claimed patient's drug dispensing appliance was invented has a simple desire to receive direct dispensing of their medication for their own use – not to meet everyone else's needs. Therefore, one skilled in the art would not have looked to (or seen) Liff or Boyer as revealing Applicant's claimed patient's appliance, since both Liff and Boyer lead one skilled in the art in a different direction – to an institutional-type device and not toward an appliance for direct, personal use by an individual patient.

Both systems of Liff and Boyer fail to address the needs of the patient, as would be seen be one skilled in the art, for simple direct dispensing of individual unpackaged doses of pharmaceuticals in an appliance sized for the patient and adapted for direct dispensing over time in a treatment regimen, as one might do at home, instead of the larger or commercial systems in Boyer or Liff. Therefore, Boyer and/or Liff do not lead one skilled in the art to Applicant's patient's appliance, but in fact, away from it.

Accordingly, one cannot combine Liff and Boyer and arrive at Applicant's independent claim 22.

For these reasons, Liff and/or Boyer, alone or in combination, fail to teach or suggest Applicant's amended independent claim 22, and therefore claim 22 is patentable and allowable over Liff and/or Boyer. Claims 25-30, and 59-61 are allowable as well based upon their dependency from claim 22.

Applicant's amended independent claim 32 specifies an intelligent drug dispensing system, which comprises at least one single patient intelligent drug dispensing appliance and a pharmaceutical replenishment request data server. The at least one single patient intelligent drug dispensing appliance includes a data network interface through which pharmaceutical replenishment request signals can be received, a controller and a reservoir configured to contain a plurality of individual doses of unpackaged pharmaceutical tablets and configured to dispense each individual dose directly to an individual patient over time according to a treatment regiment for direct use by the patient. The at least one single patient intelligent drug dispensing appliance is sized and shaped, based on the reservoir being sized to hold individual doses of the treatment regimen, for placement proximate to the patient at a non-health care facility. The pharmaceutical replenishment request data server is in communication with the data network interface to send medication replenishment request signals to the at least one single patient intelligent drug dispensing appliance.

For substantially the same reasons as presented for patentability of claim 22, Liff and/or Boyer fail to disclose Applicant's amended independent claim 32. In addition, Liff fails to disclose a pharmaceutical replenishment request data server that is operatively coupled to a data network and configured to receive pharmaceutical replenishment request messages from single patient drug dispensing appliances for causing replenishment of pharmaceuticals to single patient intelligent drug dispensing appliances, as claimed by Applicant in claim 32. Rather, as previously described, in Liff the systems are operated by physician and clinics, for physicians and clinics and therefore do not receive data messages by patients and for patients from a patient's appliance, as claimed by Applicant.

For these reasons, Liff and/or Boyer, alone or in combination, fail to teach or suggest Applicant's amended independent claim 32, and therefore claim 32 is patentable and allowable over Liff and/or Boyer. Claims 33-35 and 57 are believed to be allowable as well based upon their dependency from claim 32.

Applicant's amended independent claim 36 specifies an intelligent drug dispensing system providing automatic replenishment of pharmaceuticals. The system comprises a pharmaceutical replenishment request data server operatively coupled to a data network and configured to receive pharmaceutical replenishment request messages from at least one single

patient intelligent drug dispensing appliance via the data network, and to cause replenishment of pharmaceuticals to the at least one single patient intelligent drug dispensing appliance. The pharmaceutical replenishment request message is configured to replenish an unpackaged pharmaceutical in the at least one single patient intelligent drug dispensing appliance, the appliance apparatus including a controller and a reservoir configured to hold a plurality of individual doses of the unpackaged pharmaceutical and configured to dispense the doses over time from the reservoir directly to an individual patient in a plurality of discrete individual unit doses according to a treatment regimen for direct use by the patient, wherein the at least one single patient intelligent drug dispensing apparatus is sized and shaped for placement proximate to the patient at a non-health care facility.

For substantially the same reasons as presented for patentability of claim 22 and 32, Liff and/or Boyer fail to disclose Applicant's amended independent claim 36. In addition, Liff fails to disclose a pharmaceutical replenishment request data server that is operatively coupled to a data network and configured to receive pharmaceutical replenishment request messages from single patient drug dispensing appliances for causing replenishment of pharmaceuticals to single patient intelligent drug dispensing appliance, as claimed by Applicant in claim 36. Rather, as previously described, in Liff the systems are operated by physician and clinics, for physicians and clinics and therefore do not receive data messages by patients and for patients from a patient's appliance, as claimed by Applicant.

For these reasons, Liff and/or Boyer, alone or in combination, fail to teach or suggest Applicant's amended independent claim 36, and therefore claim 36 is patentable and allowable over Liff and/or Boyer. Claims 37-39 are believed to be allowable as well based upon their dependency from claim 36.

In the Office Action, claims 53 and 56 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shusterman U.S. Patent No. 6,471,087 ("Shusterman") in view of Boyer.

Applicant's amended independent claim 53 specifies a patients' intelligent drug dispensing appliance comprising a controller, a reservoir, a drug delivery mechanism, a data network interface, and a pharmaceutical depletion guard. The reservoir is configured to contain a supply of unpackaged pharmaceutical specific to the individual patient to be

dispensed over time according to a prescription treatment regimen, the supply including a grouped plurality of individual unit doses of tablets. The drug dispensing mechanism is coupled to and responsive to the controller and is coupled to and responsive to the reservoir, and the drug dispensing mechanism is configured to dispense the tablets of unpackaged pharmaceutical directly to the individual patient from the reservoir as individual doses over time according to the prescription treatment regimen. The data network interface is coupled to the controller. The pharmaceutical depletion guard includes a pharmaceutical level detector coupled to the controller and the data network interface, the data network interface is capable of sending a message to at least one of a health care provider and pharmaceutical supplier, the data message from the data network interface including a value of a measured amount of the tablets of unpackaged pharmaceutical in the reservoir. The intelligent drug dispensing appliance is sized and shaped, based on the reservoir being sized to hold the individual doses of unpackaged pharmacy tablets for the prescription treatment regimen, for placement proximate to the individual patient remote from a health care facility.

Shusterman fails to disclose Applicant's independent claim 53 of an intelligent drug dispensing appliance that includes a reservoir that is configured to contain a supply of unpackaged pharmaceutical to be dispensed over time to the individual patient, the supply including a grouped plurality of individual unit doses (i.e., individual unit doses grouped together within the reservoir). Instead, Shusterman discloses a compartmentalized carousel in which individual unit doses are separated from each other into different compartments and are not grouped together within a reservoir, as claimed by Applicant.

In addition, Shusterman fails to disclose Applicant's claimed intelligent drug dispensing appliance including a pharmaceutical depletion guard including a pharmaceutical level detector coupled to the controller and the data network interface, wherein the data network interface is capable of sending a message to at least one of a health care provider and pharmaceutical supplier, the data message from the data network interface including a value of a measured amount of unpackaged pharmaceutical in the reservoir.

For substantially the same reasons as previously described for patentability of claim 22, Boyer does not address unpackaged delivery of a pharmaceutical directly from a reservoir to a patient, and does not disclose a patient's drug dispensing appliance remote from a health

care facility. Boyer discloses delivering a vial to a patient, after the pharmacy fills the vial with dispenser 22.

Boyer does not cure the deficiencies of Shusterman regarding grouped unpackaged pharmaceuticals in tablet form. Boyer also does not suggest modifying its dispenser, dealing with filling vials, to handle tablet form medications separated from each other in a carousel manner, and Shusterman does not suggest modifying its system to accommodate dispensing unpackaged pharmaceutical into a vial, which is taught in Boyer.

For these reasons, Schusterman and/or Boyer fail to teach or suggest Applicant's claim 53, and therefore claim 53 is patentable and allowable over Shusterman and Boyer. Claims 54-56, 58, and 62-64 are believed to be allowable based on their dependency from claim 53.

In the Office Action, claims 65 and 66 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff in view of Boyer and further in view of Monkhouse et al., U.S. Patent No. 6,514,518 ("Monkhouse").

Applicant's independent claim 65 specifies an intelligent direct-to-patient drug dispensing appliance. The appliance comprises a controller, a reservoir, a drug delivery mechanism, and a data network interface. The reservoir is configured to contain a plurality of individual unit doses of an unpackaged pharmaceutical specific to an individual patient. The drug delivery mechanism is coupled to and responsive to the controller, and is coupled to and responsive to the reservoir. The drug delivery mechanism is configured to controllably dispense the unpackaged liquid pharmaceutical directly from the reservoir, via an ink-jet print mechanism, as a **mist for inhalation** to the individual patient as individual unit doses over time according to a prescription treatment regimen in response to signals from the controller. The data network interface is coupled to the controller. The intelligent drug dispensing appliance is sized and shaped, based on the reservoir being sized to hold the individual doses of the unpackaged liquid pharmaceutical for the prescription treatment regimen, for single patient use remote from a health care facility.

First, for the substantially the same reasons presented for the patentability of Applicant's amended independent claim 22, Liff and/or Boyer fail to teach or suggest Applicant's new independent claim 65. Moreover, both Liff and Boyer fail to disclose an

ink-jet print mechanism as a drug dispensing mechanism. Monkhouse fails to disclose **dispensing** an unpackaged pharmaceutical directly to the individual patient from a reservoir as a mist, as claimed by Applicant, with or without an ink-jet mechanism.

Moreover, Monkhouse is limited to using an ink-jet head to build a solid dosage form, such as an implant. Even if this form is a "standard format", which Applicant does not admit, it does not equate with "dispensing a mist for inhalation" as claimed by Applicant. Applicant has not claimed dispensing drugs generally in a standard format, but claimed dispensing a pharmaceutical directly to a patient as a mist for inhalation.

In particular, in Monkhouse the inkjet mechanism is used only for building the implant, not for dispensing directly to a patient. Accordingly, only after being built via three-dimensional printing (3DP), the dosage form is then dispensed to the patient, such as by implanting the solid dosage form into the patient. See Monkhouse Column 2, lines 10-24; Column 3, lines 7-8, lines 41-45. Accordingly, the ink-jet head in Monkhouse is not associated with directly dispensing a liquid pharmaceutical as a mist for inhalation by a patient – it's only associated with a **one-time** building a solid pharmaceutical for later insertion into a patient as an implant. See Monkhouse at Column 4, lines 44-48 (e.g., "printhead 22 deposits fluid 24 onto the powder layer .... And the process is repeated until the dosage forms are completed").

Applicant does not claim an implant-making appliance. Monkhouse does not disclose a direct-to-patient drug dispenser. Fluid 24 in Monkhouse is not inhaled by the patient, nor is the implant ingested by the patient. A patient does not directly receive the pharmaceutical in Monkhouse from 3DP printing, only after printing and implantation under the skin.

Accordingly, the ink jet mechanism in Monkhouse does not dispense individual doses over time according to a treatment regimen.

Moreover, there is no suggestion in either Liff or Monkhouse to modify the system of Liff or to modify the system of Monkhouse, much less combine Liff and Monkhouse to achieve Applicant's claimed system. Monkhouse and Liff are not analogous devices/systems, as one deals with dispensing bottles at an institution and the other deals with manufacturing implants. Likewise, there is no suggestion in either Boyer or Monkhouse to modify the system of Boyer or to modify the system of Monkhouse, much less combine Boyer and Monkhouse to achieve Applicant's claimed appliance. Monkhouse and Boyer are

not analogous devices/systems, as one deals with an internal pharmacy system and the other deals with manufacturing implants.

For these reasons, Liff, Boyer, and Monkhouse, alone or in combination, fail to teach or suggest Applicant's independent claim 65, and therefore claim 65 is patentable, and allowable over Liff, Boyer, and Monkhouse. Claims 50-52 and 65 are believed to be allowable based on their dependency from independent claim 65.

In the Office Action, claim 52 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Liff in view of Boyer and further in view of O'Brien U.S. Patent No. 5,963,136 ("O'Brien"). Claim 52 is believed to be patentable over Liff, Boyer and O'Brien based upon its dependency from patentably distinct claim 65, and intervening claims 50-51.

In light of the above, Applicant respectfully requests withdrawal of the rejection of all pending claims under 35 U.S.C. § 103(a).

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 22, 25-30, 32-39, 50-58, and 59-66 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claim 22, 25-30, 32-39, 50-58, and 59-66 is respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 08-2025.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to either Don Coulman at Telephone No. (541) 715-1694, Facsimile No. (541) 715-8581 or Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

Hewlett-Packard Company
Intellectual Property Administration
P.O. Box 272400
Fort Collins, Colorado 80527-2400

Respectfully submitted,

John Greeven et al.,

By their attorneys,

DICKE, BILLIG & CZAJA, PLLC
Fifth Street Towers, Suite 2250
100 South Fifth Street
Minneapolis, MN 55402
Telephone: (612) 767-2504
Facsimile: (612) 573-2005

Date: July 1, 2005
PSG: kle

Paul S. Grunzweig
Reg. No. 37,143

CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 1st day of July, 2005.

By Paul S. Grunzweig
Name: Paul S. Grunzweig